National Environmental
Laboratory **Accreditation**
Conference

PROFICIENCY TESTING

Approved June 5, 2003
Effective July 1, 2003 unless otherwise noted

Note that the NELAC standards now have two significant dates: 1) the date the standards were approved at the annual meeting, and 2) the date the standards are effective and must be implemented. This is especially important as some portions of the standards have different effective dates. The approval date is part of the document control header on each page. The cover of each chapter shows both the approval date and the effective date. Changes approved for implementation at a time other than the effective date (on the chapter cover) are noted in the chapter, showing the approved text and its effective date.

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2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS

For fields of accreditation for which proficiency testing (PT) samples are not available from a designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA) (e.g., National Institute of Standards and Technology (NIST)) accredited PT Provider, a Primary Accrediting Authority may accept PT results from non-accredited PT Providers. In these cases, the Secondary Accrediting Authority shall accept the decision of the Primary Accrediting Authority.

2.1 INTRODUCTION, SCOPE, AND APPLICABILITY

This chapter and the associated appendices define the major participating organizations and components of the NELAC PT Program. In addition to complying with the requirements of this chapter, any person, private party or government entity seeking to participate as a designated PTOB/PTPA-approved PT Provider shall also comply with the requirements of the applicable Appendices A (PT Provider Approval Criteria), B (PT Sample Design and Acceptance Guidelines), C (Proficiency Testing Acceptance Criteria), D (Proficiency Testing Oversight Body/Proficiency Test Provider Accreditor), E (Microbiology), F (Environmental Toxicology), and G (Radiochemistry). The criteria set forth in these standards shall be used by laboratories and PT Providers for the purposes of obtaining or maintaining NELAP accreditation or NELAP approval.

In addition to complying with the requirements of this chapter and appendices, any entity seeking to participate as a designated PTOB/PTPA-approved PT Provider shall also comply with all applicable requirements of "National Standards for Water Proficiency Testing Studies, Criteria Document", U.S. Environmental Protection Agency or other NELAC documents that define analytes, analyte numbers, concentrations, and acceptance criteria as required in Section C.1.1.2.

Proficiency testing (PT) is defined for the purpose of this chapter as a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. PT is not the sole criterion for determining accreditation status. Additional essential elements of the overall NELAP accreditation process, including the on-site assessment, are discussed in other chapters of the NELAC standards. The PT program is intended to cover all types of federal and State environmental analyses. However, the body of the PT standard applies primarily to chemistry.

The major components of the NELAC PT program include:

a) multiple PT Providers who shall meet stringent criteria to become approved by a Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA), as described in Section 2.3 and Appendix A;

b) specific requirements for the design of PT samples and studies, to ensure that all samples provide a consistent, fair and known challenge to laboratories seeking accreditation from a NELAP-approved Accrediting Authority, as described in Section 2.3 and Appendix B;

c) specifically defined acceptable/not acceptable criteria for evaluating PT sample results, as described in Section 2.3 and Appendix C;

d) initial approval and ongoing oversight of PT Providers by a Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA), Section 2.3 and Appendix D;

e) specific requirements for laboratories participating in PTOB/PTPA-approved PT programs, as described in Sections 2.4, 2.5, and 2.7; and,

f) oversight of all PT program activities by the PTOB(s)/PTPA(s), as described in Section 2.2.2.

2.1.1 Purpose

The PT program incorporates several practical purposes, which include:

a) the production and supply of test samples that are procedure-sensitive; that is, the samples challenge the critical components of each analytical procedure, ranging from initial sample preparation to final data analysis;

b) the production and supply of test samples that are as similar to real-world samples as is reasonably possible; it is further expected that the PT samples shall be representative of materials analyzed for environmental regulatory programs, agencies, and communities;

c) a program which is affordable by all participants;

d) the yielding of PT data that are technically defensible on the basis of the type and quality of the samples provided; and,

e) the preparation of samples such that the identification and quantitation of analytes in the samples pose equivalent difficulty and challenge regardless of the manner in which the samples are designed and manufactured by the PT Providers, e.g., samples prepared for analysis by a drinking water or wastewater method would pose equal challenge whether prepared as whole volume or as a concentrate in ampules.

2.1.2 Goals

The PT program incorporates several practical goals, which include:

a) the generation of data at a quality level required by environmental and regulatory programs;

b) the generation of data, at a minimum, comparable in quality to that of currently certified and/or accredited laboratories; and

c) the improvement of the overall performance of laboratories over time.

2.1.3 Fields of Proficiency Testing

The PT program is organized by fields of proficiency testing. The following elements collectively define fields of proficiency testing:

a) matrix,
b) technology/method, and
c) analyte/analyte group

Current NELAC fields of proficiency testing are located on the NELAC Website.

Note: Laboratories are permitted to analyze one PT sample by multiple methods for a given analyte within a technology. If a laboratory reports more than one method per technology per study, an unacceptable result for any method would be considered a failed study for that technology for that analyte.

2.2 MAJOR PT GROUPS AND THEIR RESPONSIBILITIES

The PT program structure incorporates five major groups with separate and distinct roles and responsibilities. The groups are NELAC, the PTOB/PTPA, the PT Providers, the testing laboratories, and the Primary Accrediting Authorities (AA). The lines of interaction among these groups are shown in Figure 2-1.

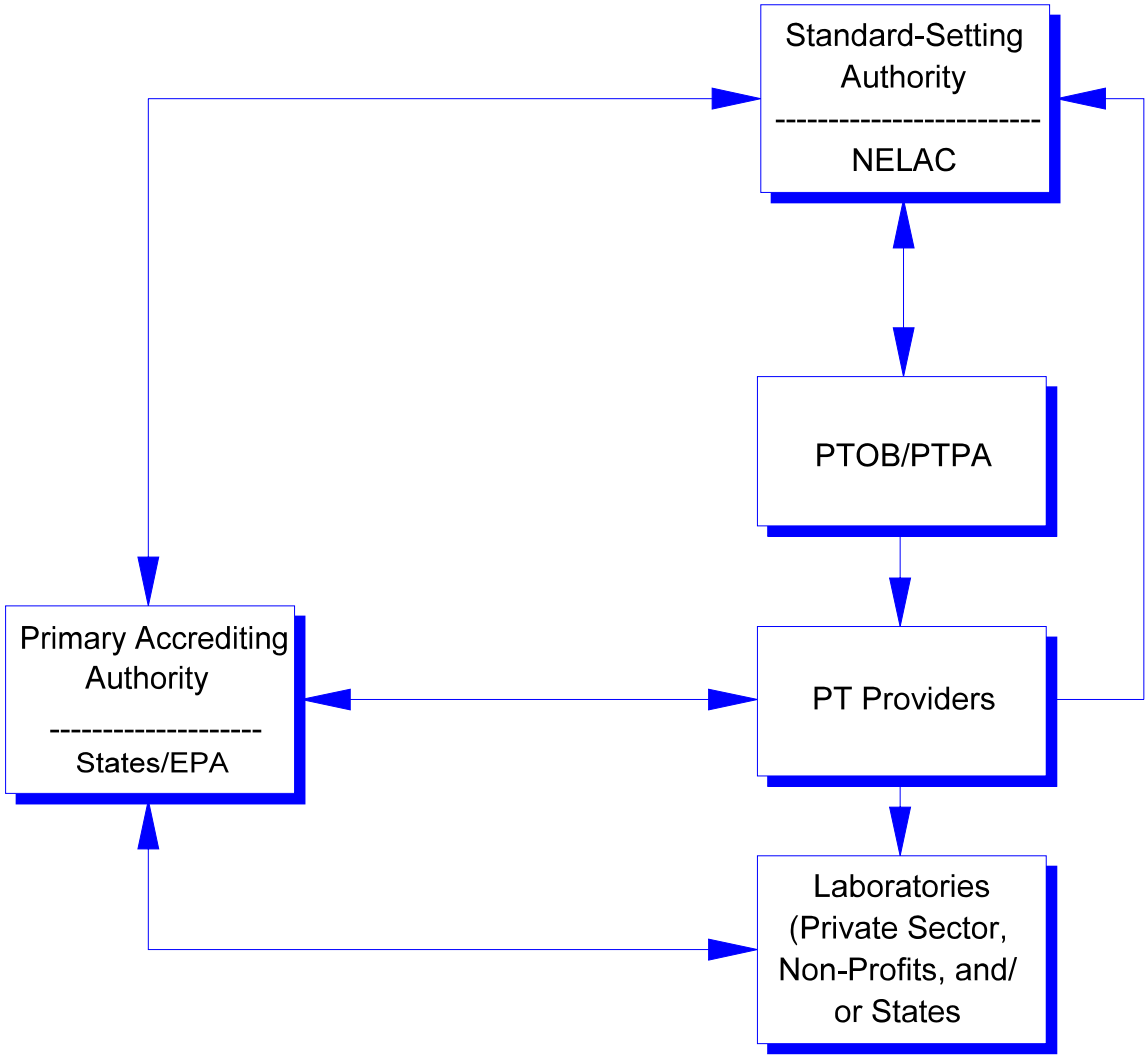

Figure 2-1. NELAP Proficiency Testing

2.2.1 Proficiency Testing Study Providers

The PT Providers shall produce and distribute PT samples, evaluate study results against published performance criteria, and report the results to the laboratories, the respective Primary Accrediting Authorities, and the PTOB/PTPA. The PT Provider shall meet the requirements of Appendix A, manufacture samples that meet the requirements of Appendix B, and score sample results in

accordance with the requirements of Appendix C. PT Providers may not supply PT samples outside their Fields of Accreditations as determined by the PTOB/PTPA.

2.2.2 Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA)

The PTOB/PTPA establishes and implements a program to accredit PT Providers and to monitor accredited providers to ensure that their studies and practices meet all applicable standards. The PTOB/PTPA shall meet the requirements of Appendix D. NELAP-recognized Accrediting Authorities may nominate an organization as a PTOB/PTPA to the NELAP-appointed Proficiency Testing Board, hereafter referred to as the PT Board. The PT Board will determine whether the organization meets the requirements of this standard and its appendices and may refer the organization to the NELAC Board of Directors to be designated as a PTOB/PTPA.

2.2.3 Laboratories

Laboratories that seek to obtain or maintain accreditation shall perform analyses of PT samples for each field of proficiency testing as defined in Section 2.1.3. PT samples shall be obtained from designated PTOB/PTPA-approved PT Providers. The laboratory shall obtain PT samples from any so approved PT Provider. The results of the analyses shall be submitted to the PT Provider for scoring.

2.2.4 Accrediting Authorities (AA)

The Primary Accrediting Authorities shall make all decisions regarding a laboratory's accreditation status. They are responsible for taking action to make these determinations including ensuring that laboratories seeking or holding their accreditations have participated in the PT program. Accrediting authorities shall accept for the purposes of initial and continuing accreditation, PT results from any designated PTOB/PTPA-approved PT Provider that meets the requirements of this standard.

2.3 REQUIREMENTS FOR PT PROVIDERS

This section and associated Appendix A describe the criteria that all PT Providers shall meet in order to be approved by the PTOB/PTPA as PT Providers. A PTOB/PTPA shall grant approval to PT Providers on a field-of-proficiency testing basis, as described in Section 2.1.3. As NELAC standards, PT acceptance criteria and codes are revised and expanded, PT providers shall modify their operations to conform. PT providers are encouraged to modify their operations as soon as possible. The timeline for implementation shall be no more than six months from the date the revisions and expansions are posted on the NELAC website.

2.3.1 PT Provider Accreditation

A provider of PT samples for NELAC accreditation must be accredited by a Proficiency Testing Oversight Body (PTOB)/PTPA that meets the NELAC PTOB/PTPA requirements contained in this Chapter and associated appendices. The PTOB/PTPA communicates the names of PT Providers that meet the NELAC requirements to the NELAC Board of Directors. A listing of organizations that meet the NELAC PTOB/PTPA requirements is available from the Chair of NELAC.

2.3.2 On-site Inspection of PT Providers

A PTOB/PTPA shall conduct an on-site inspection of any organization seeking to participate as a PT Provider, as described in Appendix D. The PTOB/PTPA shall determine whether the provider meets the applicable requirements described in this chapter and Appendices A, B, and C. Approval of a PT

Provider shall be the responsibility of a PTOB/PTPA. A PTOB/PTPA shall conduct ongoing oversight of the PT Providers as necessary to ensure conformance with all applicable standards.

2.3.3 Sample Requirements and Design

This section and associated Appendix B describe PT sample design and acceptance criteria. The matrices of all PT samples shall, to the extent possible, resemble the matrices for which the laboratory seeks to obtain or maintain accreditation. Samples may not be reused in any subsequent NELAC PT study except as described in Section 2.7.3. The PT Providers shall neither provide inappropriate assistance to the laboratories nor encourage the non-routine analysis of the PT samples.

2.3.3.1 Sample Analytes

The PT Provider shall prepare each sample lot such that the prepared concentration of each analyte in each lot is unique. The required group of analytes covering each field of proficiency testing shall be determined by the PT Board and shall be evaluated and updated, as necessary.

2.3.3.2 PT Provider Sample Testing

The PT Provider shall design, manufacture, and test the samples for homogeneity, stability, and verification of assigned values as required by Appendix B. This testing shall verify that the quality of all samples is acceptable for use in each field of proficiency testing.

2.3.4 PT Study Data Analysis

This section and associated Appendix C describe the criteria to be used by PT Providers when scoring and evaluating NELAC PT sample results.

2.3.4.1 Data Acceptance Criteria

PT Providers shall use the data acceptance criteria described in Appendix C to evaluate laboratories' PT data to ensure a laboratory's performance shall be judged fairly and consistently.

2.3.5 Generation of Study Reports

Each PT Provider shall evaluate the data and issue a report **to** the laboratories within 21 calendar days of the close of each study. The report shall be issued within the same 24 hour period to the participating laboratory and the Primary Accrediting Authority(s) as designated by the laboratory.

2.3.6 Provider Conflict of Interest

Each PT Provider shall certify that it is free of any organizational conflict of interest. A PT Provider shall never split a sample lot and offer these samples for sale as known-value check samples before the unknown samples are used in a PT study. In addition, each PT Provider shall follow procedures and have systems in place that maintain confidentiality and security of all assigned values through the closing date of each study. All records shall be retained for a period of five years.

2.3.7 Disapproval of PT Providers

A PT Provider's approval may be subjected to revocation per the procedures outlined in Appendix A, Section A.9.2.

2.3.8 PTOB/PTPA Listing of PT Providers

PTOBs/PTPAs shall maintain a list of approved PT Providers. PTOBs/PTPAs shall evaluate, update, and publish this list as specified in Appendix D.

2.4 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAM(S)

2.4.1 Required Level of Participation

To be accredited initially and to maintain accreditation, a laboratory shall participate in two single-blind, single-concentration PT studies, where available, per year for each field of proficiency testing for which it seeks or wants to maintain accreditation. Laboratories must obtain PT samples from a PTOB/PTPA-approved PT Provider. Each laboratory shall participate in at least two PT studies for each field of proficiency testing per year unless a different frequency for a given program is defined in the appendices. Section 2.5 describes the time period in which a laboratory shall analyze the PT samples and report the results. Data and laboratory evaluation criteria are discussed in Sections 2.6 and 2.7 of this chapter.

2.4.2 Requesting Accreditation

At the time each laboratory applies for accreditation, it shall notify the Primary Accrediting Authority which field(s) of testing it chooses to become accredited for and shall participate in the appropriate PT studies. For all fields of proficiency testing, including those for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a total quality management system that meets all applicable requirements of Chapter Five of the NELAC standards.

2.4.3 Reporting Results

Each laboratory shall authorize the PT Provider to release all accreditation and remediation results and acceptable/not acceptable status directly to the Primary Accrediting Authority, and the PTOB/PTPA, in addition to the laboratory.

2.5 REQUIREMENTS FOR LABORATORY TESTING OF PT STUDY SAMPLES

The samples shall be analyzed and the results returned to the PT Provider no later than 45 calendar days from the opening of the study (i.e., first day that samples are shipped or available to laboratories). The laboratory's management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed, and reported) in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities, and frequency of analysis.

When analyzing a PT sample, a laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.

2.5.1 Restrictions on Exchanging Information

Laboratories shall comply with the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study *(routine or supplemental studies)* are released:

a) A laboratory shall not send any PT sample, or a portion of a PT sample, to another laboratory for any analysis for which it seeks accreditation, or is accredited;

b) A laboratory shall not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks accreditation, or is accredited;

c) Laboratory management or staff shall not communicate with any individual at another laboratory (including intracompany communication) concerning the PT sample; and

d) Laboratory management or staff shall not attempt to obtain the assigned value of any PT sample from their PT Provider.

2.5.2 Maintenance of Records

The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for five years or for as long as is required by the applicable regulatory program, whichever is greater. These records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made available to the assessors of the Primary Accrediting Authority during on-site audits of the laboratory.

2.6 EVALUATION OF PROFICIENCY TESTING RESULTS

PT Providers shall evaluate results from all PT studies using NELAC-mandated acceptance criteria described in Appendix C. The PT Board shall provide, and update as necessary, the data acceptance criteria that all PT Providers shall use for all PT studies. Each result shall be scored on an acceptable/not acceptable basis. The PT Provider shall provide the participant laboratories and the Primary Accrediting Authority as designated by the laboratory a report showing at a minimum:

a.) Provider information:
- Provider name and PTOB/PTPA accreditation number in the header.

b.) Laboratory information:
- Laboratory name and address (location) of the laboratory, in the header. Note: This is not the address of the corporate headquarters but the address of the actual laboratory completing the testing.
- Primary Accrediting Authority ID or USEPA ID, if applicable, in the header.Name, title and telephone number of the laboratory point of contact, in the header or cover letter.

c.) Study information:
- Study number and study type, in the header.
- Opening date and closing date of the study, in the header.
- Date of amended report, if applicable, in the header.

d.) Report information:
- Analyte name for each analyte included in the standard.
- Method description.
- Laboratory value as reported.
- Assigned values and acceptance values reported to three significant figures.
- The acceptable/not acceptable status.
- A “No evaluation” score for reported values containing alpha characters.
- An indication of “Not reported” when an analyte within a PT sample is left blank.

- An indication of the length of the report, presented by either Page X of Y or the total number of pages with each page consecutively numbered.

This report shall be sent no later than 21 calendar days from the study closing date to the participating laboratories and the appropriate Primary Accrediting Authority(s) as designated by the laboratory. This report (hardcopy and electronic format) shall be sent to the laboratory and its Primary Accrediting Authority within the same 24 hour period. If the report and other PT study information is available in electronic format, it shall be available only to the designated laboratory representatives who participated in the PT study and the Primary Accrediting Authority . Upon request by either the Primary Accrediting Authorities or laboratories, the PT Provider shall make available a report listing the total number of participating laboratories and the number of laboratories scoring not acceptable for each analyte. The PT Providers shall not disclose specific laboratory results or evaluations to any other parties without the written release of the laboratory.

2.7 PT CRITERIA FOR LABORATORY ACCREDITATION

2.7.1 Result Categories

The criteria described in this section apply individually to each field of proficiency testing, as defined by the laboratory seeking to obtain or maintain accreditation in its accreditation request. These criteria apply only to the PT portion of the overall accreditation standard, and the Primary Accrediting Authority shall consider PT results along with the other elements of the NELAC standards when determining a laboratory's accreditation status. The Primary Accrediting Authority ultimately makes all decisions regarding the accreditation status of the laboratory. There are two PT result categories: "acceptable" and "not acceptable."

2.7.2 Initial or Continuing PT Studies

A laboratory seeking to obtain or maintain accreditation shall successfully complete two initial or continuing PT studies for each requested field of proficiency testing within the most recent three rounds attempted. For a laboratory seeking to obtain accreditation, the most recent three rounds attempted shall have occurred within 18 months of the laboratory's application date. Successful performance is described in Appendix C. When a laboratory has been granted accreditation status, it shall continue to complete PT studies for each field of proficiency testing and maintain a history of at least two acceptable PT studies for each field of proficiency testing out of the most recent three. For initial accreditation, the laboratory must successfully analyze two sets of PT studies, the analyses to be performed at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For continuing accreditation, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study.

Initial or continuing PT Studies must meet all applicable criteria described in this chapter and associated appendices.

2.7.3 Supplemental PT Studies

A NELAP-accredited laboratory may elect to participate in supplemental PT studies when the laboratory desires to add field(s) of proficiency testing to their scope or when the laboratory fails an initial or continuing PT study and wishes to re-establish its history of successful performance.
These additional studies are not distinguished from the initial or continuing PT studies except as described in this section.

Analysis dates of supplemental PT studies must be at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For supplemental studies, laboratories report to their PT Provider results for all analytes for which they are demonstrating corrective action or requesting an expansion of their existing accreditation.

2.7.3.1 Supplemental PT Studies for Demonstrating Corrective Action

A laboratory that has attained NELAP accreditation is required to maintain acceptable performance in PT studies conducted on a semiannual schedule. If an accredited laboratory fails to maintain a record of passing two out of the most recent three PT studies, it may be subject to loss of accreditation for one or more fields of accreditation in it's current scope of accreditation. A laboratory that is out of compliance with this PT requirement may choose to participate in a Supplemental PT Study for Demonstrating Corrective Action. Corrective Action PT samples must meet the following criteria.

a. The standard must be obtained from a PT Provider that meets the accreditation requirements of NELAC.

b. The standard must be from a lot that has been demonstrated to have met all of the design, testing, and verification requirements of Chapter 2 and associated Appendices. PT samples from previously released NELAC compliant PT studies may be used in Corrective Action PT studies so long as they are within the stability period (e.g., an expiration date) for that sample.

c. The PT provider cannot supply the laboratory with a sample that has been previously sent to the laboratory**.** The original sample tracking ID must be masked and the sample tracking ID shall be unique. (See Chapter 2, section A.5.2)

d. For corrective action supplemental studies, the assigned values for all analytes requested by the laboratory must not be equal to zero with the exception of the qualitative PCB group and qualitative microbiology.

All other aspects of Supplemental PT studies for Demonstrating Corrective Action including scoring and distribution of final reports must meet all other requirements of the NELAC PT program.

2.7.3.2 Supplemental PT Studies for Expanding an Accredited Laboratory's Scope of Accreditation

A laboratory that has attained NELAC accreditation may add fields of accreditation to its current scope of accreditation. As part of the request to expand its scope of accreditation, the laboratory is required to submit to its Primary Accrediting Authority, results of participation in two successful PT studies. The laboratory may use the results of a PT study that meets the requirements of either Section 2.7.2 or 2.7.3.1. After the laboratory is granted accreditation for the requested FOT, the laboratory is required to participate in regular semiannual PT studies.

2.7.4 Failed Studies and Corrective Action

Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records and provide to the Primary Accrediting Authority both the investigation and the action taken. If a laboratory fails two out of the three most recent studies for a given field of proficiency testing, its performance is considered unacceptable under the NELAC PT standard for that field. The laboratory shall then meet the requirements of initial accreditation as described in Section 2.7.2 - Initial or Continuing Accreditation.

2.7.5 Second Failed Study

The PT Provider shall report laboratory PT performance results to the Primary Accrediting Authority(s) as designated by the laboratory within the same 24 hour period that it reports the results to the laboratory. If a laboratory fails a second study out of the most recent three for a given analyte, as described in Section 2.7.4, the Primary Accrediting Authority shall take action, pursuant to Chapter Four, within 60 calendar days. The Primary AA shall also determine the accreditation status for all technologies/methods for which unacceptable results were reported for the analyte(s) in each matrix.

2.7.6 Scheduling of PT Studies

A Primary Accrediting Authority may specify which months that laboratories within its authority are required to participate in NELAC PT programs. If the Primary Accrediting Authority chooses to specify the months, then it shall adhere to the required semiannual schedule. If the Primary Accrediting Authority does not specify the months, then the laboratory shall determine the semiannual schedule.

2.7.7 Withdrawal from PT Studies

A laboratory may withdraw from a PT study for an analyte(s) or for the entire study if the laboratory notifies both the PT Provider and the Primary Accrediting Authority before the closing date of the PT study. This does not exempt the laboratory from participating in the semiannual schedule.

2.7.8 Process for Handling Questionable PT Samples

There may be occasions in which the PT Provider has shipped one or more samples for NELAP accreditation which do not meet the quality control requirements of Appendix B, and the provider has not in a timely manner notified all affected laboratories or Accrediting Authorities as described in Section A.10 of this standard. In this case, an AA, upon review of summary data or other relevant documentation, may choose not to use the results of the analyte(s)/matrices to support the accreditation status of the laboratories. In order to justify not using the results, the AA shall first contact the PT Provider and attempt to resolve the situation. If after notifying the PT Provider, the AA still chooses to pursue a complaint against the provider, the AA shall submit a written complaint to the PTOB/PTPA which currently accredits the PT Provider for the particular analyte(s) and matrices. The AA shall follow all procedures for filing complaints as specified by the PTOB/PTPA. If the AA is not satisfied by the response of the PTOB/PTPA which granted the accreditation, the AA shall submit a written complaint to the PT Board. The PT Board shall evaluate the complaint. If the complaint is determined to be valid, then the PT Board shall notify the PTOB/PTPA of any steps that may result in the revocation of the PTOB/PTPA being recognized by NELAP as a PTOB/PTPA.

The AA may determine that the affected laboratories shall either wait until the next regularly scheduled PT testing round to analyze another PT for that field of accreditation, or may require the laboratories to obtain and analyze a supplemental sample, and repeat the test.

PROFICIENCY TESTING
APPENDIX A

PT PROVIDER APPROVAL CRITERIA

Appendix A - PT PROVIDER APPROVAL CRITERIA

A.0 SCOPE

This appendix describes the responsibilities and requirements a proficiency testing (PT) provider shall meet in order to be a Proficiency Testing Oversight Body (PTOB) /Proficiency Test Provider Accreditor (PTPA) Approved PT Provider. In order for a PT Provider to participate in the NELAC PT program, a provider shall be approved by a PTOB/PTPA. The criteria provided below are designated to ensure the integrity and technical excellence of the NELAC PT program while allowing all qualified providers to participate in the program.

A.1 APPROVAL PROCESS

The process for approval of a PT Provider includes a biennial on-site inspection by a PTOB/PTPA to ensure that the technical criteria of this appendix are being met. At the discretion of the PTOB/PTPA, the PT Provider may be requested to confirm their ability to perform analyses within the required limits through participation in a proficiency testing program operated by the PTOB/PTPA, or through the analysis of unknown samples provided by the PTOB/PTPA. Providers are also required to submit the results of PT programs operated for NELAC to the PTOB/PTPA for review and evaluation. The PT Provider agrees to accept the findings and decisions of the PTOB/PTPA as final.

A.2 QUALITY SYSTEM REQUIREMENTS

The manufacturing quality system used by the PT Provider shall meet the requirements of both International Organization for Standardization (ISO) 9001 for the design, production, testing, and distribution of performance evaluation samples and the requirements of ISO Guide 34, Quality System Guidelines for the Production of Reference Materials. The design and operation of the PT Provider's proficiency testing program shall meet the requirements of ISO Guide 43, Proficiency Testing by Interlaboratory Comparisons. The testing facilities used to support the verification, homogeneity, and stability testing required in Appendix B of this document shall meet the requirements of both ISO 17025, (General Requirements for the Competency of Testing and Calibration Laboratories) and the relevant sections of the NELAC standards. The ability to meet the ISO 9001 quality system requirement may be fulfilled through registration of the PT Provider's quality system to American National Standards Institute (ANSI) standards by a Registrar Accreditation Board (RAB)-accredited registrar. However, a biennial on-site inspection by the PTOB/PTPA demonstrating continuing conformance is required.

A.3 PROVIDER FACILITIES AND PERSONNEL

Each provider is required to have systems in place to produce, test, distribute, and provide data analysis and reporting functions for any series of samples for which they are requesting approval. Similarly, the provider shall have in place sufficient technical staff, instrumentation, and computer capabilities as may be required by the PTOB/PTPA to support the production, distribution, analysis, data collection, data analysis, and reporting functions of the samples. No portion of the production, testing, distribution, data collection, data analysis, nor data reporting functions may be outside the control of the PT Provider for any particular study, since it is essential that the confidentiality of the samples be maintained throughout the PT study. For the purposes of this requirement "control" can mean ownership or that the subcontracted service is performed under an agreement which specifically ensures the ability of the provider to access and restrict the distribution of information related to these services. Any subcontracted services shall be assessed by a PTOB/PTPA and meet the same criteria as the PT Provider.

A.4 SAMPLE FORMULATION REVIEW

The PT Provider shall demonstrate to the PTOB/PTPA, by the submission of appropriate data, that the sample formulation for which the PT Provider is seeking approval shall permit participating laboratories to generate results that fall within the sample acceptance ranges established by the PT Board and meet the criteria of the "National Standards for Water Proficiency Testing Studies, Criteria Document" (USEPA).

A.4.1 Release of Information

In support of the requirement in Section A.4.0, PTOBs/PTPAs shall treat all sample formulation information submitted to them for review as the proprietary information of the PT Provider submitting the information. Such formulation information shall not be released by a PTOB/PTPA without the prior written consent of the PT Provider.

A.5 PROVIDER CONFLICT-OF-INTEREST REQUIREMENTS

PT Providers seeking approval shall document to the satisfaction of the PTOB/PTPA that they do not have a conflict of interest with any laboratory seeking, or having, NELAP accreditation. PT Providers shall notify the PTOB/PTPA of any actual or potential organizational conflicts of interest, including but not limited to:

a) Any financial interest in a laboratory seeking, or having, NELAP accreditation;

b) The sharing of personnel, facilities or instrumentation with a laboratory seeking, or having, NELAP accreditation.

The PT Provider is also required to inform all internal and contract personnel who perform work on NELAC PT samples of the PT Provider's obligation to report personal and organizational conflicts of interest to the PTOB/PTPA. The provider shall have a continuing obligation to identify and report any actual or potential conflicts of interest arising during the performance of work in support of NELAC PT programs. If an actual or potential organizational conflict of interest is identified during performance of work in support of NELAC PT programs, the PT Provider shall immediately make a full disclosure to the PTOB/PTPA. The disclosure shall include a description of any action which the provider has taken or proposes to take, after consultation with the PTOB/PTPA, to avoid, mitigate or neutralize the actual or potential conflict of interest. The PTOB/PTPA may reevaluate a PT Provider's approval status as a result of unresolved conflict of interest situations. Any conflict of interest disputes between the PT Provider and the PTOB/PTPA may be appealed to the NELAP Director for a final determination.

A.5.1 Ban on Distribution of Samples

PT Providers shall not sell, distribute, or provide samples used in the NELAC PT program prior to the conclusion of the study for which they were designed. Providers shall not sell, distribute, or provide samples of identical formulation and concentration to those samples which it is currently using in a NELAC study. For Supplemental PT studies for Demonstrating Corrective Action, the requirements in section 2.7.3.1 of the standard shall apply.

A.5.2 Procedures for Tracking Studies

PT Providers must have procedures in place to track which laboratories have received which studies if the PT Providers are following section 2.7.3.1. These procedures shall include a written SOP and specific, auditable tracking methods.

A.6 CONFIDENTIALITY OF PT STUDY DATA

The PT Provider shall demonstrate to the PTOB/PTPA that it has systems in place to ensure that the confidentiality of data associated with NELAC PT samples and programs are not compromised. PT Providers shall not release the assigned value of any sample currently being used in a NELAC PT study prior to the conclusion of the study.

A.7 DATA REVIEW AND EVALUATION

The NELAC designated PTOB/PTPA shall review the data from PT Provider's studies to ensure that acceptance limits used to evaluate laboratories are consistent with national standards as established by NELAC. The PTOB/PTPA shall also evaluate the performance of the PT Providers by monitoring, and reporting, to both the providers and the PT Board the pass/fail rates of all providers on all samples tested. A PTOB/PTPA is required to investigate any PT Provider whose pass/fail rate is statistically different from the national average.

A.8 COMPLAINTS & CORRECTIVE ACTION

The PT Provider shall prepare a written summary of all written complaints regarding technical aspects of the studies and the corrective action taken for every complaint. This report shall be available to the PTOB/PTPA on demand. All PT Provider complaints that remain unresolved after 90 days shall be referred to the PTOB/PTPA.

A.9 LOSS OF PROVIDER APPROVAL

PT Providers who fail to meet the requirements of these standards may be subject to loss of their approval as a NELAC PT Provider. Providers may lose approval to provide individual sample sets based upon review of PT study data by a PTOB/PTPA as required in Appendix A, Section A.7. Similarly, PT Providers who fail to meet the requirements of Appendix A, Sections A.2 through A.6, on a continuous basis may lose their approval as a PTOB/PTPA-approved PT Provider for all samples.

A.9.1 Periodic Review of PT Providers

A PTOB/PTPA may at any time, review the performance of any approved PT Provider against these standards. Based upon this review, the PTOB/PTPA may decide that the approval status of a PT Provider be revoked, adjusted, limited, or otherwise changed based upon failure to meet one or more of the specified requirements.

A.9.2 Revocation of Approval

Should a PTOB/PTPA propose to revoke or suspend a provider's approval for failure to meet the requirements of these standards, the PTOB/PTPA shall inform the provider of the reasons for the proposed revocation or suspension and the procedures for appeal of such a decision. The due process rights of the provider shall be protected during any revocation or suspension proceedings. The final decision on the revocation or suspension of a provider's approval to supply PT samples for

the NELAP accreditation resides with the Director of NELAP. If the provider loses PTOB/PTPA approval it shall lose NELAP approval to supply samples for the NELAC PT program.

A.10 NOTIFICATION OF SAMPLE INTEGRITY

The PT Pprovider is responsible for notifying all laboratories, PTOB/PTPA and Primary Accrediting Authorities designated by the laboratory when a particular analyte was determined not to meet the requirements of Appendix B within 21 calendar days of the study closing date.

PROFICIENCY TESTING
APPENDIX B

PT SAMPLE DESIGN
& ACCEPTANCE GUIDELINES

Appendix B - PT SAMPLE DESIGN & ACCEPTANCE GUIDELINES

B.0 INTRODUCTION

An integral element of the NELAC PT program standards is the assurance of PT samples which are of high quality, well documented, homogeneous, and stable. To meet the goals of NELAC, the PT samples used in the program shall also provide all laboratories with samples which offer a consistent challenge. All PT samples shall meet all applicable specifications of these standards.

B.1 SAMPLE FORMULATION APPROVAL

The PT Provider shall demonstrate the adequacy of sample formulation to the satisfaction of the PTOB/PTPA. The criteria for formulation adequacy are that the sample shall provide equivalent challenge to the laboratories under test as similar samples for the same parameters as other providers, and that the sample shall exhibit laboratory acceptance rates, measured as provider percentage pass/fail performance, consistent with other samples used in the program for the same parameters.

B.1.1 Adequacy of the Sample Formulation

The testing and verification protocol required to establish sample equivalency shall be agreed to by both the PT Provider and the PTOB/PTPA on a case-by-case basis. It is the responsibility of the PT Provider to demonstrate the adequacy of sample formulation to the satisfaction of the PTOB/PTPA.

B.1.2 PT Sample Composition

One or more specific analyte(s) may not be included in a sample, yet those analyte(s) shall be counted and scored with the analytes that are present in the PT study. The value assigned to these unspiked analytes would be zero. The PT Provider shall prepare samples including a minunum number of analytes according to the following criteria:

a) PT samples that are to be scored for one to ten analytes must include all of these analytes.

b) PT samples that are to be scored for ten to twenty analytes must include at least ten of these analytes or 80% of the total, whichever number is greater.

c) PT samples that are to be scored for more than twenty analytes must include at least sixteen of these analytes, or 60% of the total analytes, whichever number is greater.

d) If following (b) or (c) above and a percentage of the total number of analytes in the sample is a fraction, the fraction shall be rounded up to the next whole number. For example: 16 analytes × 0.80 = 12.8 = 13 analytes in sample.

e) PT Providers shall use a random selection process to determine which parameters will be assigned zero values within any given PT sample.

All other PT samples must contain all the analytes of interest within the concentration ranges as required by this standard.

B.1.3 PT Sample Matrix

Refer to the NELAC Glossary for definition of matrices. Note: PT samples are not currently available for all matrices. Refer to the NELAC field of proficiency testing lists for sample availability.

B.1.4 PT Sample Composition for Solid Matrices

Soil PT samples shall be well-characterized natural soil and cannot contain 100% sand.

B.2 VERIFICATION OF ASSIGNED VALUE

All PT samples used for obtaining or maintaining NELAP accreditation shall be analyzed by the PT Provider prior to shipment to the laboratories to ensure suitability for use in the program. The assigned value of the sample shall be used to establish acceptance criteria, and it shall be verified by analysis. PT Providers shall verify the assigned value by direct analysis against National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM), if a suitable NIST SRM is available for use. If a NIST SRM is not available then verification shall be performed against an independently prepared calibration material. An independently prepared calibrant is one prepared from a separate raw material source, or one prepared and documented by a source external to the provider.

B.2.1 Relative Standard Deviation of Verification Analysis

The method used by the PT Provider for verification analysis shall have a relative standard deviation of not more than 50% of the relative standard deviation predicted at the assigned value by the laboratory acceptance criteria being used by NELAC for each parameter. The relative standard deviation of the provider's verification method shall be established by a method validation study, and the suitability for use shall be approved by the NELAP designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA).

B.2.2 Quality Control Check of the Assigned Value

The assigned value for every parameter in all PT samples shall be verified by analysis. The assigned value of the analyte is verified if the mean of the verification analyses is within 1.5 standard deviations, as calculated as described in Sections C.1.1.1 or C.1.1.2, of either a) the assigned value if an unbiased verification method is used or b) the mean value for the analyte as calculated in Sections C.1.1.1 or C.1.1.2 if a biased method is used. The standard deviation of the verification analyses also shall be less than one standard deviation as calculated in Sections C.1.1.1 or C.1.1.2. For analytes that are evaluated using fixed percentages as defined in Section C.1.1.1, standard deviations are calculated by assuming that the fixed percentage is equal to two standard deviations.

B.3 HOMOGENEITY TESTING

PT sample homogeneity is essential to ensuring that all laboratories are treated fairly. Therefore, the purpose of the homogeneity testing procedure is to establish at the 95% confidence level that all samples distributed to the laboratories have the same assigned value for every parameter to be evaluated. Homogeneity testing is required on all PT samples prior to sample shipment to the laboratories.

B.3.1 Homogeneity Testing Procedure

The homogeneity of the samples shall be established using a generally accepted statistical procedure. The procedure selected by the PT Provider shall be capable of evaluating the relative consistency of each analyte across the production run, and shall be performed on the final packaged samples. The procedure shall establish at the 95% confidence level that the assigned value is consistent across the production run. Samples, or parameters, which fail to pass the homogeneity testing criteria cannot be used in the NELAC PT program to evaluate laboratories.

B.3.2 Suitable Homogeneity Testing Procedures

A suitable homogeneity testing procedure shall be capable of comparing the between sample to within sample standard deviation across the PT Provider's packaging run, and shall ensure comparability with 95% confidence. Suitable homogeneity testing procedures are available in both ISO Guide 35 for the Certification of Reference Materials and in the ISO Reference Material Committee (REMCO)-Association of Official Analytical Chemists (AOAC) Harmonized Protocol for the Proficiency Testing of Analytical Laboratories. However, the homogeneity testing procedure used by the PT Provider shall be approved for use by the PTOB/PTPA.

B.4 STABILITY TESTING

The samples used in the NELAC PT program shall be verified as stable for the period of each study. Therefore, the stability of all samples and parameters shall be established by the PT Provider following the close of data submission from the laboratories. The samples are considered stable for the period of the study if the mean analytical value as determined after the study for each parameter falls within the 95% Confidence Interval calculated for the prior to shipment verification testing used to establish the assigned value. The testing procedure used for stability testing shall be approved for use by the PTOB/PTPA.

B.5 DATA REPORTING BY PT PROVIDERS

The results of sample assigned value verification, homogeneity, and stability testing for each PT study shall be available ONLY to the designated laboratory representatives participating in that study. All data developed by the provider in support of verification testing, homogeneity testing, and stability analysis shall be provided to any laboratory participating in the program upon request after the close of the study. Providers shall supply PT data to the Primary Accrediting Authorities, as per Section 2.6, in a format acceptable to the Primary Accrediting Authority.

B.5.1 Verification and Homogeneity Reports

The data developed by the PT Provider in support of verification and homogeneity testing shall be supplied in summary format to the PTOB/PTPA in an electronic format to be determined by the PTOB/PTPA. Verification and homogeneity data shall be supplied to the PTOB/PTPA prior to sample distribution to the laboratories.

B.5.2 Laboratory Data and Stability Reports

All summary data from the laboratories and the results of stability testing shall be provided to the PTOB/PTPA in an electronic format to be determined by the PTOB/PTPA within 30 calendar days of the close of the study.

PROFICIENCY TESTING
APPENDIX C

PT ACCEPTANCE CRITERIA
AND
PT PASS/FAIL CRITERIA

Appendix C - PT ACCEPTANCE CRITERIA AND PT PASS/FAIL CRITERIA

C.0 PURPOSE, SCOPE, AND APPLICABILITY

This appendix defines the criteria to be used by any entity which seeks to participate as a NELAP-designated PTOB/PTPA-approved Proficiency Test Provider for scoring the results obtained from the analyses of samples in any NELAC PT study. The PT Providers shall submit all laboratories' performance rating(s) to the Primary Accrediting Authority, as described in Chapter Two of the NELAC standards, to be used as a tool for determining a laboratory's accreditation status. PT acceptance limits and pass/fail criteria are established on a field of proficiency testing basis.

C.1 ANALYTE ACCEPTANCE LIMITS

Acceptance limits are established for each analyte as described in this appendix. The tables containing all analyte acceptance limits established by the PT Board and from the USEPA Criteria Document shall be posted on the NELAC Website and reviewed annually by the PT Board.

C.1.1 Analyte Acceptance Limit Categories

Acceptance limits are separated into two categories. Results for analytes with acceptance limits determined as described in Sections C.1.1.1 and C.1.1.2 shall be used in the determination of a laboratory's field of proficiency testing pass/fail evaluation. Results for analytes with acceptance limits determined as described in Section C.1.1.3 shall not be used as part of the field of proficiency testing acceptable/not acceptable evaluation.

C.1.1.1 Drinking Water, Waste Water, and Ambient Water Analytes with USEPA Established Acceptance Limits

PT Providers shall utilize the proficiency test acceptance limits that have been established by USEPA in the "National Standards for Water Proficiency Testing, Criteria Document" where they apply. The "National Standards for Water Proficiency Testing, Criteria Document" is incorporated into this appendix by reference.

C.1.1.2 Analytes with Acceptance Limits Established by the PT Board

For analytes not included in the "National Standards for Water Proficiency Testing, Criteria Document," Proficiency Test providers shall use acceptance limits established by the PT Board and shall be made available to PTOB/PTPA-approved PT Providers by the Director of NELAP. Data from sources such as the USEPA Proficiency Evaluation (PE) studies, interlaboratory results from professional organizations such as ASTM, other Proficiency Test Providers, commercial and non-profit organizations, shall be used to establish the evaluation criteria. All evaluation criteria shall be approved by the PT Board prior to use by a PTOB/PTPA-approved PT Provider.

C.1.1.3 Experimental Data: Analytes without Promulgated Acceptance Limits or Established Regression Equations

For those analytes not included in categories C.1.1.1 or C.1.1.2, e.g., newly regulated analytes, or analytes in a matrix that have not been fully evaluated in interlaboratory studies, NELAC acceptance limits shall be established only after interlaboratory data has been collected for a minimum of one year unless the PT Board determines that sufficient data have been collected in less time. The data obtained during the one-year period shall be referred to as "experimental data". The PT Board shall derive regression equations to be used to establish acceptance limits for analytes in the experimental

category after sufficient data have been collected. The laboratory shall receive a copy of its own experimental data from the PT Provider at the conclusion of the PT study.

C.2 ACCEPTABLE PT RESULTS FOR CHEMICAL ANALYTES IN POTABLE WATER AND NON-POTABLE WATER PT SAMPLES

A laboratory's PT analyte result is acceptable when it falls within the regulatory promulgated acceptance limits (Section C.1.1.1). For Section C.1.1.2 analytes, PT Providers shall use the PT sample's verified assigned value and said regression equations to determine the mean and standard deviation. Acceptance limits shall be set at the mean ± two standard deviations for potable water analytes and the mean ± three standard deviations for non-potable water analytes. A result is acceptable when it falls within these derived acceptance limits.

C.3 NOT ACCEPTABLE PT RESULTS FOR POTABLE WATER AND NON-POTABLE WATER PT SAMPLES

A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:

a) the result falls outside the acceptance limits;

b) the laboratory reports a result for an analyte not present in the PT sample (i.e., a false positive); or,

c) the laboratory does not withdraw from a study as described in Section 2.7.7, and fails to submit its results to the PT Provider on or before the deadline for the PT study.

C.4 ADDITIONAL REQUIREMENTS FOR PT PROVIDERS

PT Providers shall examine all data sets for bimodal distribution and/or situations where results from a given method have disproportionally large failure rates or reporting anomalies to the Proficiency Testing Oversight Body/Proficiency Test Provider Accreditor. If bimodal or multimodal distribution is found and acceptance criteria are calculated using robust statistical analysis, data should be scored by method specific robust statistical analysis. All proficiency test data are to be submitted to the PTOB/PTPA in the format specified by the PTOB/PTPA and shall be reviewed annually by the PT Board for the purpose of revising existing and establishing new evaluation criteria.

C.4.1 Additional Matrix/Analyte Groups

Additional matrices and/or analytes may be added to the NELAC PT fields of testing at the request of any Accrediting Authority, USEPA program office, or PTOB / PTPA-approved PT Provider. The request for the addition of an analyte must include at a minimum ten sets of interlaboratory data on the analyte in the particular matrix. Each data set must contain a minimum of twenty valid data points. The PT Board shall review the data and develop an initial set of laboratory acceptance limits based upon the needs of the Accrediting Authorities, USEPA, and the laboratories. Laboratory acceptance limits developed by the PT Board on any new matrix/analyte combinations shall be reviewed annually by the PT Board. The purpose of this annual review is to ensure that the limits represent the actual capabilities of the laboratories. For any additional matrix or analyte groups added to the NELAC field of proficiency testing by the PT Board, laboratories shall complete two successful PT studies within 12 months of the date the additional groups were added.

C.5.0 NELAC PT Study Pass/Fail Criteria

NELAC PT studies are designed to meet the requirements of Chapter 2 and associated appendices. Once data acceptability has been determined as described in Sections C.1 through C.3 of this appendix, the laboratory's PT "Pass" or "Fail" evaluation is determined as described in this section. Pass/Fail criteria are used when groups of analytes are evaluated as a unit for the laboratory's initial demonstration of proficiency.

C.5.1 Analyte Group PT Studies

Analyte Group PT Studies are those that are analyzed using methods in which the ability to correctly identify and quantitate a series of analytes is indicative of the laboratory's ability to correctly determine the presence or absence of similar analytes. Analyte groups shall be as defined in the Accrediting Authority quality systems manual and published on the NELAC website.

C.5.2 Promulgated USEPA Pass/fail Criteria

In all cases, promulgated EPA pass/fail criteria, e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1), will be used as NELAC PT pass/fail criteria as applicable. The criteria described in Section C.5.3 shall be used in the absence of promulgated USEPA pass/fail guidelines.

C.5.3 Pass/fail Criteria For Analyte Group PT Samples

Proficiency testing pass/fail evaluations for Analyte Group PT studies shall be determined as follows. To receive a score of "Pass", a laboratory must produce "Acceptable" results as defined in Section C.1 for 80% of the analytes in an Analyte Group PT Study. Greater than 20% "Not Acceptable" results shall result in the laboratory receiving a score of "Fail" for that group of analytes. For example, a laboratory must report all "Acceptable" results for an Analyte Group PT Study containing 1-4 analytes, may report no more than one "Not Acceptable" result for a study containing 5-9 analytes, two "Not Acceptable" results for a study containing 10-14 analytes. A "Not Acceptable" result for the same analyte in two out of three consecutive PT studies shall also result in the laboratory receiving a score of "Fail" for that analyte. The PCB analyte group is exempt from the 80% pass/fail criteria.

PROFICIENCY TESTING
APPENDIX D

PROFICIENCY TESTING OVERSIGHT BODY/ PROFICIENCY TEST PROVIDER ACCREDITOR

Appendix D - PROFICIENCY TESTING OVERSIGHT BODY/ PROFICIENCY TEST PROVIDER ACCREDITOR

D.0 PURPOSE, SCOPE, AND APPLICABILITY

This appendix defines the qualifications, scope of responsibilities and requirements for a NELAP designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA) as defined in Section 2.2.2 of the NELAC document. In addition to complying with the requirements of this appendix, a PTOB/PTPA, for this oversight function, shall comply with the applicable requirements described in Chapter 2 and its associated Appendices. NELAP-recognized Accrediting Authorities may nominate an organization as a PTOB/PTPA to the PT Board. The PT Board will determine whether the organization meets the requirements of this standard and its appendices and may refer the organization to the NELAC Board of Directors to be designated as a PTOB/PTPA.

D.1 TECHNICAL AND ADMINISTRATIVE QUALIFICATIONS

An organization shall demonstrate to the PT Board by the submission of a current Statement of Qualifications that it has the technical expertise, administrative capacity, and financial resources sufficient to implement and operate a national program of PT Provider evaluation and oversight. In the event that the organization is not a nationally or internationally recognized authority, the PT Board reserves the right to request further documentation detailing the organization's qualifications. The organization shall meet the following general requirements:

a) Demonstrate the capability to manage and evaluate complex environmental reference materials in a variety of matrices;

b) Demonstrate expertise in statistical applications as related to large interlaboratory performance evaluation programs;

c) Demonstrate the capability to conduct on-site audits of PT Providers;

d) Demonstrate the capability to conduct technical reviews of Initial Applications;

e) Demonstrate a knowledge and understanding of the ISO guides 9001, 34, 43, and Chapter Two of the NELAC standards including Appendices A, B, and C.

D.2 PTOB/PTPA RESPONSIBILITIES REGARDING INITIAL ASSESSMENT OF PT PROVIDERS

PTOB/PTPA responsibilities are described in this section. The primary responsibility of a PTOB/PTPA is the oversight and ongoing monitoring and evaluation of the PT Providers. The oversight activities of a PTOB/PTPA shall be designed to ensure that the PT Provider meets the requirements specified in Chapter Two and Appendices A, B and C. Any variations from these requirements shall be approved by the PT Board prior to a body being approved as a NELAC PTOB/PTPA. All activities described herein shall be conducted by a PTOB/PTPA.

D.2.1 Development of Standard Operating Procedures and Forms

PTOBs/PTPAs shall develop the Standard Operating Procedures (SOPs) necessary to conduct the PT Provider evaluation process. These documents shall be based upon the requirements of Chapter Two of the NELAC standards and the associated Appendices A, B, and C. The PT Board the authority to review and approve, as necessary, the SOPs developed by a PTOB/PTPA.

D.2.1.1 SOP(s) for the Assessment Process

The PTOB/PTPA shall develop and implement SOP(s) including but not limited to: the initial application submittal and review process, on-site inspection, submittal of final reports to NELAP, the procedures for determining that a PT Provider's approval be revoked, the procedures for appealing approval determinations, and any other procedures deemed necessary by NELAC.

D.2.1.2 Initial Application

A PTOB/PTPA shall develop the initial application process to be submitted by PT Providers applying for approval as PT Providers of NELAC samples. The application shall include questions regarding the qualifications of the organization seeking approval. In addition to completing the initial application process, a PTOB/PTPA shall require that the PT Provider submit copies of its current ISO 9001 registration certificate or any other documents which detail the quality systems required by the provisions of Chapter Two and associated appendices.

D.2.1.3 SOP(s) for On-site Inspections and Checklist(s)

A PTOB/PTPA shall develop SOP(s) for conducting consistent, effective, on-site inspections of PT Providers. The SOP shall include policies which describe the circumstances for conducting any additional inspections, and circumstances for determining whether on-site inspections shall be announced or unannounced. A PTOB/PTPA shall develop standard, consistent checklist(s) to be used during any and all inspections of PT Providers.

D.2.2 Initial Application Review and On-site Inspections

A PTOB/PTPA shall follow the procedures described in this section for the review of applications and on-site inspections of any candidate PT Provider.

a) A PTOB/PTPA shall review the initial application documents, described in D.2.1.2, for compliance with the PT Provider qualifications described in Appendix A and other applicable documents.

b) A PTOB/PTPA shall review the sample designs used by the PT Provider for compliance with Appendix B and other applicable documents.

c) A PTOB/PTPA shall review the PT analyte and sample scoring procedures used by the PT Provider for compliance with Appendix C and other applicable documents.

d) Following the review of the Initial Application and associated documents, a PTOB/PTPA shall conduct an on-site inspection of the PT Provider. The PT Provider shall be provided with checklist(s) to be used during the inspection as part of the initial application process.

e) Following the inspection, a PTOB/PTPA shall conduct an exit meeting with the PT Provider, which shall include discussion of deficiencies and discrepancies found; however, a PTOB/PTPA may further revise the findings after the closing of the exit meeting, if necessary.

   The inspection shall include, at a minimum:

   1) Review of the quality system for adherence to the requirements of Appendices A, B and C;

   2) Review of staff qualifications and technical expertise necessary to produce acceptable proficiency testing samples;

3) Review of the sample manufacturing and verification procedures to ensure that the requirements of Appendices A and B are met;

4) Review of the procedures in place to ensure that all personnel are aware of and abide by standards of conduct for PT Providers and confidentiality of sample values; and,

5) Review of data reporting systems to ensure that the requirements of Appendix C are met within the time periods specified in Chapter Two.

f) A PTOB/PTPA shall send a draft report to the PT Provider after the completion date of the inspection. A PTOB/PTPA shall allow the PT Provider to review and comment on the draft if the PT Provider finds any discrepancies and determines that revisions are necessary. A PTOB/PTPA shall then submit a final inspection report to the PT Provider after the completion of the on-site inspection. The final report may only contain discrepancies and findings identified during the on-site inspection or discussed during the exit briefing.

g) A PTOB/PTPA shall allow the provider to submit their response to the report. In order for the provider's response to be considered acceptable, a PTOB/PTPA shall require that it include a description of corrective actions necessary to meet the criteria of Chapter Two, and Appendices A, B, and C.

D.3 PTOB/PTPA RESPONSIBILITIES REGARDING APPROVAL OF PT PROVIDERS

A PTOB/PTPA shall utilize the appropriate final report and associated documents submitted by the PT Provider to grant or deny approval to that provider.

D.4 PTOB/PTPA RESPONSIBILITIES FOR ONGOING OVERSIGHT OF PT PROVIDERS

A PTOB/PTPA shall conduct oversight of all approved PT Providers. The oversight may include:

a) the use of referee laboratories to verify the concentrations of analytes in randomly selected PT Provider samples;

b) the statistical monitoring of PT Provider's study data to detect occurrences which indicate samples of unacceptable quality, i.e., failure rates that exceed expected norms, analyte standard deviations that exceed expected intervals, and analyte mean recoveries which are significantly above or below historical trends. The ongoing monitoring criteria to be used by a PTOB/PTPA shall be developed by NELAC.

c) biennial on-site inspections of the PT Provider review and monitoring of critical operational parameters of the PT Provider, i.e., change in senior management, sale of the company.

d) on-site inspections of the PT Provider for cause.

Based upon the results of its ongoing oversight, the PTOB/PTPA may determine that the provider's approval status be reevaluated.

D.5 DEVELOPMENT AND MAINTENANCE OF A COMPREHENSIVE PT DATABASE

A comprehensive PT database shall be developed and maintained by the PTOB(s)/PTPA(s) in conjunction with NELAC.

D.6 COMPLAINTS AND CORRECTIVE ACTION

A PTOB/PTPA shall evaluate all complaints that it receives regarding either approved or candidate PT Providers. If the PTOB/PTPA determines that a complaint warrants investigation, the PTOB/PTPA shall notify the provider of the complaint. The PT Provider is required to resolve the complaint to the satisfaction of the PTOB/PTPA. A PTOB/PTPA shall provide to the PT Board a summary of all PT Provider complaints received the previous year.

D.7 LIST OF APPROVED PT PROVIDERS

A PTOB/PTPA shall maintain a list of approved PT Providers and their Fields of Accreditation. The list shall be maintained on a continuing basis on an electronic bulletin board or similar means and shall be readily available to laboratories seeking NELAP accreditation, State Accrediting Authorities and other interested parties. PT Providers shall agree to abide by the provisions of NELAC regarding the advertising and marketing use of the designation, "NELAP-designated PTOB/PTPA Approved Proficiency Test Provider".

D.8 SPONSORSHIP OF ANNUAL *NELAC PROFICIENCY TESTING CAUCUS*

The PTOB(s)/PTPA(s) shall, in conjunction with NELAC, sponsor an annual *NELAC Proficiency Testing Caucus*. The *Caucus* shall, if possible, be held in conjunction with the annual NELAC meeting. The purpose of the *Caucus* is to provide a forum for PT Providers, Accrediting Authorities, laboratories, federal agencies, and other interested parties to exchange information regarding the PT study results of the previous year. The *Caucus* shall include technical presentations and open discussions on means to improve the proficiency testing aspect of NELAC with a continuing goal of improving the quality of environmental data generated by the NELAC accredited laboratories.

D.9 PTOB/PTPA ETHICS

This section describes the overall ethics and standards of conduct that shall be adhered to for a PTOB/PTPA to implement and administer a successful PT Provider oversight program. A PTOB/PTPA shall serve as an impartial body designed to objectively evaluate information about PT Providers and use this information to make sound determinations regarding providers' approval status. A PTOB/PTPA shall be able to certify to any interested party that it is free of any organizational or financial conflict of interest, which would prevent it from complying with the requirements of Appendix D. A PTOB/PTPA shall remain unbiased in evaluating information gathered and received including inspection reports, referee sample results, complaints, and any other information obtained regarding a PT Provider. The PTOB/PTPA shall evaluate all information gathered and received about a provider related to providing NELAC PT samples, and determine which information is relevant to the approval status of a provider, and provide that information to NELAP, the Primary Accrediting Authorities, the laboratories, and the public as appropriate.

D.10 CONFIDENTIALITY

A portion of the information provided to a PTOB/PTPA by the PT Provider in the course of its inspection and oversight activities shall be proprietary in nature. A PTOB/PTPA shall agree to maintain the confidentiality of proprietary information provided to it by the PT Provider.

PROFICIENCY TESTING
APPENDIX E

MICROBIOLOGY

Appendix E - MICROBIOLOGY

E.0 PURPOSE

This appendix outlines the requirements for microbiological proficiency testing under the Safe Drinking Water Act (SDWA) and the Clean Water Act (CWA). Microbiological testing for other USEPA programs shall be added as required. Semi-annual proficiency testing is required per the schedule contained in Section 2.4.

E.1 SAMPLES

E.1.1 SDWA Samples

PT Providers shall present samples either as full volume samples or preparations easily reconstituted to full volume samples. For the SDWA, there shall be ten 100+ ml. samples (as presented or after reconstitution) for the qualitative determination (Presence/Absence) of total coliform and fecal coliform (or *E. coli*). Sample sets which are provided to the laboratories shall contain bacteria that produce the following:

- Verification as total and fecal coliforms (E. coli).
- Verification as total coliforms, but not as fecal coliforms.
- Bacterial contaminates which shall not verify as total or fecal coliforms.

Furthermore, each set shall contain the following samples:

- One to four samples containing an aerogenic strain of Escherichia coli for total and fecal coliform positive results using all USEPA approved methods.
- One to four samples containing Enterobacter sp. or other microorganisms ensuring a total coliform positive and fecal coliform negative result using all USEPA approved methods.
- One to four samples containing Pseudomonas sp. or other microorganisms ensuring a total and fecal coliform negative result using all USEPA approved methods.
- One to four blank samples.
- Optionally, one sample for the quantitative determination of Heterotrophic Plate Count.

Sample sets for qualitative analysis shall be randomly composed of samples that are Total coliform absent, Total coliform only present and Fecal coliform (E. coli) present.

E.1.2 CWA Samples

For the CWA, one sample shall be provided for the quantitative determination of Total coliform or Fecal coliform. Providers may require laboratories to analyze samples during a fixed time period after sample shipment or at any time during the testing period which shall not exceed the time limit set in Chapter Two.

E.2 SAMPLE PREPARATION AND QUALITY CONTROL

Proficiency test sample providers shall select bacterial strains and *holding media* that produce the appropriate biochemical reactions for *all* approved analytical methods. This shall be documented by

analyses performed by the provider prior to sample shipment. The provider shall also demonstrate that the samples are stable by analysis of a randomly selected set either after the study closing date or in the case of a study with a fixed testing period, on the last working day of the testing period.

E.3 SCORING

E.3.1 Qualitative Analyses, *SDWA Samples*

Participating laboratory results shall be considered Acceptable or Unacceptable when compared to the known presence or absence of total coliform or fecal coliform (or *E. coli*) bacteria. Passing shall be considered as nine out of ten samples having acceptable results, and no false negatives reported.

E.3.2 Quantitative Analyses

Quantitative result data sets shall be evaluated by analytical method using standard statistical analysis with outlier rejection. Most Probable Number data shall be transformed to logs prior to statistical analysis. Acceptable results are those that are within the interval defined by the mean plus or minus two standard deviations for SDWA analytes or within the 99% confidence limits as set by the mean, standard deviation and set size *(n)* for their respective data set for all other analytes.

E.3.2.1 Requirement for Quantitative Data Set Size

Each PT Provider's microbiological data set shall be comprised of at least 20 valid data points for each method evaluated. Sample sets of less than 20 data points may be used only with the approval of the PTOB/PTPA.

PROFICIENCY TESTING
APPENDIX F

ENVIRONMENTAL TOXICOLOGY

Appendix F - ENVIRONMENTAL TOXICOLOGY

F.0 PURPOSE, SCOPE, AND APPLICABILITY

This appendix defines the criteria applying the proficiency testing (PT) program to the following environmental toxicology programs: 1) whole effluent toxicity, 2) sediment toxicity, and 3) soils toxicity.

F.1 RATIONALE

Accreditation for environmental toxicology testing laboratories shall be based on Proficiency Testing and on-site audits, the latter including but not limited to an evaluation of personnel qualifications, facility acceptability, quality system and standard operating procedures, status of data/reports generated and routine reference toxicant testing. Proficiency Testing provides a snapshot of the laboratory's capability; however, due to the number of variables inherent to environmental toxicology testing it will not carry the same weight as PT samples for chemical analytes for an interim period of duration yet to be determined. PT samples shall be comprised of unknown concentrations of EPA's historical reference toxicant materials. Every effort shall be made by the PTOB/PTPA working together with the providers to reduce the number of variables in each method (i.e., organism age, etc.) while following the language of various protocols.

F.2 LABORATORY ENROLLMENT IN PROFICIENCY TESTING PROGRAMS

F.2.1 Required Level of Participation

Laboratories seeking accreditation for environmental toxicology shall participate in at least one PT study per year, when available, for each method code as designated (method code includes matrix, organism, exposure system, and endpoint).

F.2.2 Requirements for Laboratory Testing of PT Study Samples

a) Analyze within 45 calendar days of sample receipt; report results within 45 calendar days of completion.
b) Samples shall be analyzed in the same manner as routine samples within the limits of the method code.

F.3 PT CRITERIA FOR LABORATORY ACCREDITATION

F.3.1 Initial and Continuing Accreditation

Laboratories which seek to obtain or maintain accreditation for environmental toxicology shall complete at least one PT sample per year for a given field of accreditation (i.e., not more than 12 months apart) and at least 15 calendar days apart (i.e., participation in a second round or remedial study may not occur within 15 calendar days of the first or failed study). Failure to meet the annual schedule shall be regarded as a failed study.

F.4 Fields of Proficiency Testing

The environmental toxicology PT program shall be organized by fields of proficiency testing based on method [including matrix, test organism, and exposure system and endpoint(s)]. Laboratories may choose to participate in one or more PT fields of accreditation, or portions thereof.

F.4.1 Whole Effluent Toxicity (WET)

Laboratories seeking WET accreditation shall be assessed through on-site assessment and evaluation of EPA Discharge Monitoring Report - Quality Assurance (DMR-QA) test results when available. During this interim period, a failed DMR-QA endpoint shall require: 1) a formal response to the Accrediting Authority (AA) with an explanation of probable cause for the endpoint failure and description of corrective actions to be taken (where appropriate) and 2) a decision by the AA to accept the response or require additional actions on the part of the laboratory and/or the AA. There shall be no loss of accreditation based solely on PT results during this interim period.

If a laboratory's response is unacceptable and the AA does not require additional on-site assessments the laboratory is required to complete another study. Such additional studies must be conducted, at least 15 calendar days from the previous PT study, until the results are acceptable to the AA. The AA may conduct additional on-site assessments as necessary based on the results of any additional studies. The default for the WET PT program is accreditation without PT samples.

Interim method codes shall reflect the EPA DMR-QA study codes for the current study year.

PROFICIENCY TESTING
APPENDIX G

RADIOCHEMISTRY

Appendix G - RADIOCHEMISTRY

G.0 PURPOSE

This appendix contains the NELAC requirements for radiochemical proficiency testing under the Safe Drinking Water Act (SDWA). The appendix supplements the requirements of Chapter 2 and Appendices A, B, and C with requirements specific for NELAC radiochemical proficiency testing studies.

Radiochemical proficiency testing for other USEPA Programs shall be added as the necessary resources, proficiency testing objectives and supporting data are available.

Other pertinent information concerning the SDWA radiochemical proficiency testing samples are available from the Executive Director of NELAP.

G.1 PROFICIENCY TESTING PROVIDER LICENSING

Possession, transfer and use of many radioactive materials is regulated by the Nuclear Regulatory Commission (NRC) or State radiological departments. The PT Provider shall ensure that they are licensed not only for the possession and use of radioactive materials in their facility but also for the explicit distribution of these materials in commerce.

G.2 SDWA SAMPLE DESIGN

The PT Provider must ensure that the sample design used for the SDWA radiochemical PT samples meets the applicable criteria contained in the USEPA's "National Standards for Water Proficiency Testing Studies, Criteria Document".

G.2.1 ASSIGNED VALUES

Assigned values must be within the ranges established by the USEPA in the "National Standards for Water Proficiency Testing Studies, Criteria Document", where they apply. Assigned values are selected such that the concentration of each analyte will vary over time throughout the concentration range. The PT Provider must also ensure that the method for selecting an assigned value meets the applicable criteria contained in the EPA's "National Standards for Water Proficiency Testing Studies, Criteria Document". The assigned value is determined based on the mass of standard added to the volume of water as follows:

Assigned value (pCi/L) = pCi activity added ÷ volume preserved water ÷ dilution factor.

G.3 SCORING

The results from a participating laboratory testing under the SDWA are classified as "Acceptable" or "Not Acceptable" based on the criteria in US EPA's "National Standards for Water Proficiency Testing Studies, Criteria Document". The tests in the document include an evaluation of the average of the required three independent determinations for each radionuclide in the study and an evaluation of the range of the three results for each radionuclide. Acceptance limits are provided in the "NELAC PT Acceptance Limits for Radionuclides" table which is located on the NELAC website.

G.4 STUDY TIMETABLES

Semi-annual proficiency testing is required per the schedule contained in Section 2.4. The samples shall be analyzed and the results returned to the PT Provider within the applicable time frames specified in the USEPA's "National Standards for Water Proficiency Testing Studies, Criteria Document."

PROFICIENCY TESTING
APPENDIX H

PERFORMANCE TESTING REQUIREMENTS FOR FIELD AIR MEASUREMENT

Appendix H - PERFORMANCE TESTING REQUIREMENTS FOR FIELD AIR MEASUREMENT

H.0 INTRODUCTION: PURPOSE, SCOPE, AND APPLICABILITY

This Appendix defines the criteria to be used by any entity which seeks to participate as a Proficiency Test Provider and score the results obtained from the analyses of samples in an air measurement NELAC PT Study. This appendix specifically covers performance testing (PT) requirements for Source and Ambient air field measurement conducted for regulatory compliance.

There are two categories of performance testing performed for compliance related air sample field measurement: 1) calibration-based performance testing conducted for field instruments for which delivery of a representative, quality controlled PT sample is not practical, and 2) performance testing for field instruments for which delivery of a representative, quality controlled PT sample is possible. For example, EPA Method 5 is used to collect (on a batch, time-integrated basis) particulate matter from stationary emission sources. The equipment metering box and probe are calibrated per the method prior to and then upon its return from the field after sampling is completed. During its use in the field there is no practical means of introducing a controlled PT sample (category 1 example). In contrast, continuous emission monitors (CEMs) for both ambient air and source emission monitoring can be challenged with a PT gas in a cylinder to determine performance of that instrument during its operation in the field (category 2 example).

In category 1 for field measurements in which the delivery of acceptable and appropriate PT samples is not possible, calibration and maintenance requirements outlined in Chapter 5 Quality Systems or Chapter 7 Field Activities will be used to assure the quality and representativeness for field measurement data.

This standard is being developed only for the category 2 performance testing of field measurements where delivery of a standard PT sample is possible. Calibration-based performance testing will be a subset of either the NELAC Quality Systems or Field Activities Chapters, as appropriate.

For field measurements that fall under this standard, two distinct sets of scoring criteria are defined: 1) whether or not an individual analyte result is either “Acceptable” or “Not Acceptable” and 2) whether or not a laboratory’s initial PT performance for a group of interdependent analytes can be evaluated as “Pass” or “Fail.” The PT Providers will submit all field measurement performance rating(s) to the Primary Accrediting Authority, as described in Chapter 2 of the NELAC standards, to be used as a tool for determining a laboratory’s accreditation status. PT acceptance limits and pass/fail criteria are established on a field of proficiency testing basis.

H.1 Proficiency Testing for Field Air Measurement

Field air measurements refer to measurements taken in the field for regulatory compliance. Examples include continuous emission monitors (CEM) used to obtain real-time measurements of emissions from industrial point source discharges or from ambient air monitoring. Also included are gaseous organic emissions by gas chromatography (GC) and Fourier transform infrared (FTIR) spectroscopy real-time monitors used to monitor criteria pollutants at a Superfund site fence line..

NELAC intends to develop PT criteria for relevant field measurements. The criteria will be developed to mirror PT criteria for laboratory sample analysis; however, for many field measurements, delivery of representative, quality controlled PT samples will be problematic. The standard will be developed to address those field measurements for which PT sample delivery is possible. For field measurements in which delivery of acceptable PT samples is not possible, calibration and

maintenance requirements outlined in Ch. 5 Quality Systems will be used to assure the quality and representativeness of field measurement data.

H.2 ACCEPTANCE LIMITS

Acceptance limits are established for each analyte. Whether or not a laboratory has passed or failed a group of interdependent analytes is based on the number of results that are determined to be acceptable.

H.2.1 Analyte Acceptance Limit Categories

Acceptance limits are separated into two categories. Results for analytes with acceptance limits determined as described in Sections H.2.1.1 and H.2.1.2 shall be used in the determination of a laboratory's field of proficiency testing pass/fail evaluation. Results for analytes with acceptance limits determined as described in Section H.2.1.3 shall not be used as part of the field of proficiency testing pass/fail evaluation.

H.2.1.1 Analytes with USEPA Established Acceptance Limits (Prepared ± fixed percentage or Mean ± 2 standard deviations)

PT Providers shall utilize the proficiency test acceptance limits that have been established by USEPA in the National Standards for air proficiency testing studies where they apply. The National Standards are incorporated into this Appendix by reference. EPA's established proficiency test acceptance limits for chemical analytes are typically expressed in the following manner:

Prepared ± fixed percentage. Acceptance limits shall be set at plus and minus the published fixed percentage of the analyte's verified prepared value.

Mean ± 2 standard deviations. The PT Board has a process for establishing linear regression equations relating a PT samples prepared value to mean and prepared value to standard deviation, acceptance limits shall be set using said equations and the sample's verified prepared value. Linear regression equations may only be used for prepared values that fall within the range of prepared values used to establish said equations. In the event that there are no linear regression equations available for a given analyte, that analyte shall be treated as described in Section H.2.1.3.

H.2.1.2 Analytes with acceptance limits derived from regression equations established by the PT Board

When USEPA Program regulations for establishing acceptance criteria are not available Proficiency Test providers shall set acceptance limits using regression equations that predict the mean and standard deviation for an analyte in a given range of concentrations. Regression equations shall be derived by the PT Board and shall be made available to PTPA-approved PT Providers by the Executive Director of NELAP. Data from sources such as the USEPA PE studies, interlaboratory results from professional organizations such as ASTM, other proficiency testing providers, commercial and non-profit organizations, shall be used to establish the equations. All regression equations shall be approved by the PT Board prior to use by a PTPA-approved PT Provider. For these analytes, the PT Provider shall use the sample's verified prepared value and said equations to determine the mean and standard deviation.

H.2.1.3 Experimental Data: Analytes without promulgated acceptance limits or established regression equations

For those analytes not included in categories H.2.1.1 or H.2.1.2, e.g., newly regulated analytes, or analytes in a matrix that have not been fully evaluated in interlaboratory studies, NELAC acceptance limits shall be established only after interlaboratory data has been collected for a minimum of one year unless the PT Board determines that sufficient data have been collected in less time. The data obtained during the one-year period shall be referred to as "experimental data." The PT Board shall derive regression equations to be used to establish acceptance limits for analytes in the experimental category after sufficient data have been collected. The laboratory shall receive a copy of its own experimental data from the PT Provider at the conclusion of the PT study.

H.3 ACCEPTABLE PT RESULTS FOR CHEMICAL ANALYTES IN FIELD AIR PT MEASUREMENTS

Criteria for acceptable results for will be dependent on the precision and accuracy of the accepted field measurement method. A laboratory's PT analyte result is acceptable when it falls within the regulatory promulgated acceptance limits (Section H.2.1.1). For Section H.2.1.2 analytes, PT Providers shall use the PT sample's verified prepared value and said regression equations to determine the mean and standard deviation. Acceptance limits shall be set at the mean ± two standard deviations for ambient air or source sample analytes. A result is acceptable when it falls within these derived acceptance limits.

H.4 NOT ACCEPTABLE PT RESULTS FOR SOURCE AND AMBIENT PT SAMPLES

Criteria for acceptable results for will be dependent on the precision and accuracy of the accepted field measurement method. A laboratory's result for any analyte is considered unacceptable if it meets any of the following criteria:

a) The result falls outside the USEPA's promulgated acceptance limits (Section H.2.1.1) or outside prediction interval derived from established regression equations;

b) The lab reports a result for an analyte not present in the PT sample (i.e., a false positive);

c) The lab reports a result of "Not Detected", (or similar indication of no detection), for an analyte present in the PT sample (i.e., a false negative);

NOTE: If a laboratory reports a result less then the lowest concentration contained in the NELAC-approved PT concentration range for an analyte present in the PT sample at a concentration within the NELAC-approved PT concentration range, the result shall be classified as a false negative and scored as "not acceptable".

d) The lab fails to submit its results to the PT Provider on or before the deadline for the PT study.

H.5 NELAC PT STUDY PASS/FAIL CRITERIA

NELAC PT samples are designed to meet the requirements of Chapter 2 and associated appendices. Once data acceptability has been determined as described in Sections H.1 through H.3 of this appendix, the laboratory's PT "Pass" or "Fail" evaluation is determined as described in this Section. Pass/Fail criteria are used when groups of interdependent analytes are evaluated as a unit for the laboratory's initial demonstration of proficiency.

H.5.1 Interdependent Analyte PT Samples

Interdependent analyte PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate a series of analytes is indicative of the laboratory's ability to correctly determine the presence or absence of similar analytes.

An example of interdependent PT analytes includes GC monitoring of a suite of VOC analytes using EPA Method 18.

H.5.2 Non-interdependent Analyte PT Samples

Non-interdependent PT Samples are those that are analyzed using methods in which the ability to correctly identify and quantitate an analyte or a series of analytes in a sample is not indicative of the laboratory's ability to correctly identify and quantitate similar analytes. Non-interdependent analyte PT samples may contain a single analyte, or may contain multiple analytes. Currently, non-interdependent analytes are not expected to apply to the air matrix.

H.5.3 Promulgated USEPA Pass/fail Criteria

In all cases, promulgated USEPA pass/fail criteria, e.g., drinking water volatiles as listed in 40 CFR 141.61(a), subsection (m)(1), shall be used as NELAC PT pass/fail criteria as applicable. The criteria described in Section 5.4 shall be used in the absence of promulgated USEPA pass/fail guidelines.

H.5.4 Pass/fail Criteria For Interdependent Analyte PT Samples

Proficiency Testing pass/fail evaluations for Interdependent Analyte PT samples shall be determined as follows. To receive a score of "Pass", a laboratory must produce "Acceptable" results for XX% of the analytes in an Interdependent Analyte PT Sample. Greater than 100-XX% "Not Acceptable" results shall result in the laboratory receiving a score of "Fail" for that series of analytes. For example, a laboratory must report all "Acceptable" results for an Interdependent Analyte PT Sample containing 1-4 analytes, may report no more than one "Not Acceptable" result for a sample containing 5-9 analytes, two "Not Acceptable" results for a Sample containing 10-14 analytes. A "Not Acceptable" result for the same analyte in two consecutive PT studies shall also result in the laboratory receiving a score of "Fail" for that analyte.

H.5.5 Pass/fail Criteria For Non-Interdependent Analyte PT Samples

For non-interdependent analytes one unacceptable result would be failing for laboratory analysis. Currently, non-interdependent analytes are not expected to apply to the air matrix.